IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:
The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.
Case No. 18-op-45090

and

The County of Cuyahoga v. Purdue Pharma L.P., et al.
Case No. 1:18-op-45004

MDL No. 2804

Hon. Dan A. Polster

REPLY MEMORANDUM IN FURTHER SUPPORT OF DISTRIBUTOR DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON PROXIMATE CAUSATION GROUNDS

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In an effort to create the appearance of disputed issues of fact, Plaintiffs submitted an 82-page omnibus opposition to Defendants' separate causation motions ("Opposition"). Notwithstanding the Opposition's extensive citations to the discovery record and expert reports, it does not come forward with any evidence that ***Distributors*** caused Plaintiffs' harms. Most notably, Plaintiffs have not come forward with any evidence that they were harmed as a result of shipments to "pill mill" doctors or illicit pharmacies that should have been blocked by Distributors. Instead, the evidence cited by Plaintiffs falls into three main buckets—each of which is entirely irrelevant either to Plaintiffs' claims against Distributors or to causation:

1. Plaintiffs devote the vast majority of their Opposition to detailing Manufacturers' allegedly fraudulent marketing. But Plaintiffs admit that Distributors played no part in that campaign. Accordingly, the Opposition's extensive discussion of the purported causal relationship between marketing and Plaintiffs' injuries is irrelevant as to Distributors.

2. Plaintiffs purport to have evidence of Distributors' alleged violation of supposed duties under the Controlled Substances Act ("CSA"). But that evidence is relevant, if anything, to the question whether Distributors breached a duty—not causation. To establish causation, it is not sufficient for Plaintiffs to show that Distributors violated the CSA, or even to identify particular orders that they say were excessive. Rather, Plaintiffs would need evidence of diversion in Summit or Cuyahoga Counties—and to tie that evidence to Distributor misconduct, on the one hand, and their injuries, on the other. They never do that.

3. Plaintiffs cite expert evidence purportedly establishing a causal link between (i) increased opioid prescribing and dispensing, and (ii) increased opioid mortality. But Plaintiffs' own experts explain why Distributors are ***not*** responsible for that increase. If, as Plaintiffs' experts say, the overwhelming majority of pharmacy orders were based on good-faith prescribing by doctors (albeit prescribing that allegedly was tainted by Manufacturer marketing), then Distributors' purported failure

to conduct adequate diligence on those orders to detect possible diversion did not cause Plaintiffs' injuries. While Plaintiffs claim that, in retrospect, many of those prescriptions were not medically necessary, their own evidence shows that, when viewed through a contemporaneous lens, the prescriptions were appropriate under the prevailing standard of care. Accordingly, no matter how much diligence Distributors did, the orders would have shipped because they related to legitimate prescribing—and Distributors have no duty and no ability to prevent patients from receiving the medicines prescribed in good faith by their doctors. Plaintiffs have no answer to this argument.

Distributors also are entitled to summary judgment on causation grounds for another, independent reason: any connection between their alleged wrongdoing and Plaintiffs' injuries is impermissibly attenuated and remote. Distributors' opening brief established by undisputed record ***evidence*** that the pills Distributors ship to pharmacies would sit on the shelf, causing harm to no one, but for the intervening acts of (1) doctors who write opioid prescriptions for their patients, (2) pharmacists who dispense opioid medicines to patients, (3) patients or third parties who criminally divert opioid medicines to illicit use, and (4) end-users who criminally use opioids for a non-medical purpose. Plaintiffs offer no evidence in response to Distributors' showing. Under established Sixth Circuit precedent, the intervening conduct of these multiple independent actors conclusively demonstrates the absence of proximate causation as to Distributors. This applies with particular force to the extent that Plaintiffs' claims are based not on the prescription opioids supplied by Distributors, but on the abuse of heroin and illicit fentanyl supplied by drug cartels.

I. THERE IS NO EVIDENCE THAT DISTRIBUTORS' ASSERTED FAILURE TO CONDUCT ADEQUATE DUE DILIGENCE CAUSED PLAINTIFFS' INJURIES.

Distributors' opening brief demonstrated that Plaintiffs have no evidence that Distributors' alleged conduct caused Plaintiffs' injuries. In response, Plaintiffs declare that they "have offered considerable expert testimony, supported by significant circumstantial evidence, and admissions by the Defendants themselves that Defendants' failures led directly to the harms within Plaintiffs'

communities." Opp. 66. But the "evidence," to the extent any is cited at all, does not bear on whether Distributors' conduct caused injuries to Plaintiffs.

First, Plaintiffs spill considerable ink on their assertion that Distributors violated a purported "duty" under the CSA to identify "suspicious" orders and "refrain from shipping such orders unless and until they confirm that the orders are not likely to be diverted." Opp. 19. Even if Distributors had such a duty,[1] and even if that "duty" could be enforced by Plaintiffs,[2] and even if Distributors violated the supposed duty,[3] that evidence does not establish that the violation ***caused harm to Plaintiffs***. In addition to proving Distributors' wrongdoing, Plaintiffs must come forward with evidence tying any such wrongdoing to their asserted injuries.[4] Because they have not done so, Distributors are entitled to summary judgment.

Second, Plaintiffs claim to have "circumstantial evidence" tying Distributors' alleged CSA violations to their harm, Opp. 66, but they do not actually cite any "circumstantial evidence" establishing causation ***as to Distributors***. They do not identify even a single instance of diversion occurring within the Plaintiff Counties as a result of any "excessive shipments" by Distributors—let alone point to evidence demonstrating that the diversion was a factor in causing Plaintiffs any harm. Indeed, Plaintiffs' diversion expert admits that he has no "knowledge of what happened to any of the drugs that were distributed." Rafalski Tr. 582:9–19 (Dkt. 1969-19); *see also* Pls.' Consol. Opp. to Defs.' Mot. to Exclude McCann and Rafalski at 2 (Dkt. 2112) (admitting that McCann and Rafalski "do *not* offer opinions about the number of orders that were in fact diverted, nor are they required to do so").

While Plaintiffs assert that they "were flooded with diverted opioids," Opp. 68, they offer ***no***

[1] They did not. *See* CSA Duties Br., (Dkt. 2159).

[2] It cannot. *See* Negligence Per Se Br. (Dkt. 1861); Preemption Br. (Dkt. 1883).

[3] They did not. *See* CSA Compliance Br. (Dkt. 2149).

[4] Plaintiffs devote many pages to detailing the purported insufficiencies of Distributors' suspicious order monitoring systems. *See, e.g.*, Opp. 18–19, 22–25, 60, 65–66. But those purported deficiencies are relevant, if anything, to the question whether Distributors breached supposed "duties" under the CSA; they are entirely irrelevant to the question of causation.

evidence of diversion as a result of "excessive shipments" by Distributors. They point to a handful of pharmacies that they say received too many pills, Opp. 68–69, but an increase in orders is not the same thing as diversion. Merely identifying purported failures in Distributors' suspicious order monitoring systems—or even orders that Distributors supposedly should not have shipped—does not demonstrate that Distributors caused (or were a "substantial factor" in causing) Plaintiffs' harm.[5]

Third, Plaintiffs point to an "association between increases in opioid supply and the increase in prescription opioid deaths" to demonstrate causation. Opp. 70; *see id.* 78 ("more pills lead to more deaths"). But that argument ignores Plaintiffs' own explanation for why the increase occurred. According to Plaintiffs and their experts, diversion by "pill mill" doctors (who knowingly wrote illegitimate prescriptions) or illicit pharmacies (who dispensed in the absence of a legitimate prescription) played only a very small role in bringing about the opioid crisis.[6] Rather, the increase in the number of opioid prescriptions written by doctors and filled by patients was, they say, overwhelmingly brought about by Manufacturers' over-promotion of opioids. *See, e.g.*, Opp. 1–18, 25–26, 51–53, 60–65, 71, 74–76. Manufacturers' marketing campaign, Plaintiffs assert, was so pervasive and effective that it changed the standard of care for the treatment of chronic pain, causing doctors to write more and more opioid prescriptions (at higher and higher doses) based on a good-faith belief that this was the appropriate course of treatment. *See* Br. 7–11.[7]

If Plaintiffs are correct that the increase in the number of pills was due to an increase in good-

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[5] Nor do the so-called "admissions" relied on by Plaintiffs establish causation. For example, Plaintiffs point to testimony from McKesson, Cardinal Health and AmerisourceBergen employees agreeing that diversion "can happen" if a registrant does not follow the CSA or that "an increase in a drug's availability in the marketplace may be a factor that attracts interest by those who abuse and divert drugs," *see* Opp. 43–44, 67, Carney Tr. 27:14–28:14 (Dkt. 2169-9), but none of those supposed admissions does anything to demonstrate that diversion occurred *in Summit or Cuyahoga Counties* as a result of Distributors' alleged excessive shipments or that improper shipments of opioids by Distributors caused Plaintiffs to incur a single penny of additional expense.

[6] *See, e.g.*, Lembke Rpt. at 12 (Dkt. 2000-10) (Plaintiff expert opining that "opioid overprescribing is not the result of a small subset of so-called 'pill mill' doctors . . . but rather has been driven by a wholesale shift in medical practice").

[7] Plaintiffs admit that Distributors played no role in the alleged marketing campaign. *See* Opp. 1–2; Pls.' Civil Conspiracy, RICO, and OCPA Opp. at 3, 14 (Dkt. 2182).

faith prescribing pursuant to the prevailing standard of care by doctors (albeit prescribing allegedly influenced by marketing), then Distributors are not a cause of either the increase or the downstream consequences of that increase. As Distributors explained in their opening brief, they have no obligation (and no authority) to prevent patients from receiving FDA-approved medicines prescribed in good faith by their doctors (at whatever dose and in whatever quantity the doctors deemed appropriate). In other words, if doctors are writing prescriptions for what they believe to be legitimate medical purposes, even if they are writing too many of them, Distributors have no "duty" under the CSA to flag those orders or to prevent those patients from receiving the medicines the doctors prescribed.[8] As a consequence, if Distributors had conducted the additional diligence Plaintiffs say should have been done to detect potential diversion, all they would have discovered is that the orders related to legitimate prescriptions, which they had no duty (or right) to stop. This remains so even if the doctors' good-faith belief that the prescriptions were medically appropriate was mistaken or tainted by an alleged marketing campaign in which Distributors played no part. *See* Br. 11–13.

For this reason, the doctrine of "concurrent causation" and the "substantial factor" test, *see* Opp. 34, 59, are of no help to Plaintiffs. If a doctor wrote a prescription in good faith, but was influenced in part by Manufacturers' allegedly fraudulent marketing, then the concurrent causes of any resulting injury might include both the doctor and the Manufacturers. But Distributors are not a cause—concurrent or otherwise—of any injury flowing from that good-faith prescribing. Nor is Distributors' conduct—delivering to DEA-registered pharmacies pills used to fill legitimate prescriptions—a "substantial factor" in causing Plaintiffs' harm.

[8] Accordingly, Distributors cannot be liable if pills prescribed for legitimate medical use (1) cause the patient to whom they were prescribed to become addicted, or (2) are subsequently sold or given away by the patient. Distributors likewise cannot be liable if a thief steals the pills from the patient's medicine cabinet. *See* Moran Tr. 54:1–55:25 (Dkt. 1968-7) (Narcotics Detective with the Cleveland Division of Police agreeing that Distributors are not to blame for diversion that occurs when someone steals unused pills from a family member and them "sells them or uses them themselves").

Finally, while Plaintiffs point to various expert reports and say they establish causation, the expert opinions referenced in the Opposition either have nothing to do with Distributors or have nothing to do with causation. None establishes, even on an aggregate basis, that Distributors' purported failure to conduct due diligence on "suspicious orders" caused any injury to Plaintiffs:[9]

- **Dr. Rosenthal.** According to Plaintiffs, Dr. Rosenthal "uses economic modeling to quantify the extent to which the increased sales of prescription opioids were caused by Defendants' unlawful marketing." Opp. 26. Notwithstanding Plaintiffs' use of the term "Defendants," it is clear that her opinions are limited to ***Manufacturers'*** alleged marketing conduct. Rosenthal Rpt. ¶ 11 (Dkt. 2000-23). Dr. Rosenthal does not offer any opinions regarding Distributors. Rosenthal Tr. 750:2–6 (Dkt. 1970-12).
- **Ms. Keller.** Ms. Keller opines that ***Manufacturers*** should have identified certain orders placed by pharmacies in the Plaintiff Counties as "suspicious." She does not offer any opinions whatsoever regarding Distributors. Keller Rpt. ¶¶ 22–35 (Dkt. 2000-7).
- **Dr. McGuire.** Dr. McGuire purports to quantify Plaintiffs' damages. He does not opine on, or support in any way, the proposition that Distributors' conduct caused Plaintiffs' injuries—he ***assumes*** that. Rather, he attempts to quantify the costs incurred by Plaintiffs to deal with opioid-related issues and attributes portions of those costs to Defendants based on inputs he receives from other Plaintiff experts. McGuire Rpt. at 6, 9, 11–12 (Dkt. 2000-17); McGuire Tr. 196:11–24, 203:22–204:14 (Dkt. 1966-21).
- **Dr. Whitelaw.** Dr. Whitelaw opines that certain Distributors' "compliance programs" were insufficient. Whitelaw Rpt. at 53–236 (Dkt. 2000-26). But that is a liability opinion. Dr.

[9] Plaintiffs offer an extensive defense of their reliance on "statistical analysis of aggregate data" to show causation. Opp. 44–53. Whatever the merits of that argument, it is irrelevant *as to Distributors* because Plaintiffs do not offer any proof—aggregate or otherwise—of a causal relationship between Distributors' wrongdoing and their harm.

Whitelaw does not even purport to opine that Distributors' supposed compliance deficiencies caused Plaintiffs any harm. *Id.* at 2.

- **Dr. Gruber.** Dr. Gruber purports to show a causal connection between (i) the number of prescription opioid doses shipped to a given community and (ii) opioid abuse, mortality and crime. Gruber Rpt. ¶ 12 (Dkt. 2000-6). But, as explained above, if the increased shipments were driven by good-faith prescribing in accordance with the then-prevailing standard of care, then Distributors were not the cause of any harm flowing from that increase.[10]

- **Dr. McCann.** Dr. McCann calculated, using five different methodologies, the number of orders that Distributors purportedly should have flagged as "suspicious," and thus as requiring additional due diligence before they could be shipped. McCann Rpt. ¶¶ 130–52, 160 (Dkt. 2000-14). Those methodologies, however, were provided by counsel. McCann Tr. 134:13–17 (Dkt. 1966-17). In particular, counsel instructed Dr. McCann to ***assume*** that, after an order placed by a pharmacy is flagged as suspicious under a given methodology, all future orders from that pharmacy should likewise be flagged as suspicious. *Id.* at 140:12–141:12; *see also* McCann Rpt. ¶ 132. Dr. McCann does not himself opine on the correctness of those methodologies or counsel's instructions. McCann Tr. 522:7–11.

- **Mr. Rafalski.** Mr. Rafalski opines that one of the five calculation methodologies used by Dr. McCann "provides a reasonable estimate and an initial trigger and first step to identifying orders of unusual size." Rafalski Rpt. at 40–41, 46 (Dkt. 2000-22). He does not, however, opine that all—or any—of the orders meeting this "initial trigger" for further due diligence were diverted to illicit use. To the contrary, Mr. Rafalski admits that he (1) cannot identify

[10] Like Dr. Gruber, Dr. Cutler also purports to demonstrate a correlation between (i) the number of prescription opioid doses shipped to a given community, and (ii) opioid mortality. Cutler Rpt. ¶ 11 (Dkt. 2000-4). That supposed showing is likewise irrelevant as to Distributors for the same reasons.

"any particular order" that "was diverted to an illicit channel" or "led to someone's addiction, overdose or death" in the Plaintiff Counties, Rafalski Tr. 508:1–18, and (2) cannot identify (even in the aggregate) "the number of opioid pills that entered [the Counties] unlawfully," *id.* at 208:11–17. He cannot do this because he has no "knowledge of what happened to any of the drugs that were distributed to each of the pharmacies." *Id.* at 528:15–19. Lacking any such knowledge, Mr. Rafalski cannot opine that Distributors' shipments led to diversion—let alone that the shipments caused Plaintiffs any harm. This conclusion is not altered by Mr. Rafalski's unadorned "belief"—untethered to any facts or evidence—that diversion was "probable." *See id.* at 189:8–191:2.

- **Dr. Cutler.** Dr. Cutler purports to be able to estimate the "portion of the harm" resulting from Manufacturers' "marketing misconduct" that "could have been avoided" had Distributors acted to "prevent" shipments "unrelated to medical need." Cutler Rpt. App. III.J at 1; *see* Cutler Tr. 80:5–21, 84:20–22, 594:11–595:3 (Dkt. 1961-9, 1961-10). Specifically, he purports to be capable of deriving percentages of opioid mortality that were driven by the shipments that should have been flagged for additional diligence. Cutler Rpt. App. III.J at 2–5; Decl. of David Cutler ¶ 9 & App. A (Dkt. 2210-1).[11]

As Distributors established in their opening brief, no Plaintiff expert—including Dr. Cutler—opines that Distributors' alleged failure to conduct adequate due diligence resulted in any pharmacy orders being shipped that would not have shipped if there had been adequate due diligence. *See* Br.

[11] While Dr. Cutler's report stated that he was capable of performing this calculation, it did not actually do so. Instead, it relied solely on *assumptions provided by counsel* to estimate the "share of shipments for which the distributors are liable." Cutler Rpt. App. III.J at 3; *see* Br. 12 n.29. While Dr. Cutler subsequently provided a declaration that purported actually to perform the calculation—using figures provided by Dr. McCann under the methodology endorsed by Mr. Rafalski, *see* Cutler Decl. ¶ 9 n.15 & App. A, that declaration appropriately was stricken by Special Master Cohen as untimely, *see* E-mail from S.M. Cohen (Aug. 13, 2019, 9:46 PM EDT) (on file with author). Accordingly, Plaintiffs have no evidentiary support whatsoever for their experts' supposed estimate of the share of harms attributable to Distributor misconduct.

12. For this reason, it is simply not the case that Dr. Cutler provides an estimate of harms that could have been avoided if Distributors had acted properly, as Plaintiffs suggest. *See* Opp. 57, 59. In reality, Dr. Cutler at most identifies (in his now-stricken declaration, *see supra* n. 11) only the portion of harm that would have been avoided if Distributors had refused to ship all orders that supposedly should have been flagged for additional diligence under the "initial trigger" endorsed by Mr. Rafalski and employed by Dr. McCann.[12] That is not sufficient to prove causation.

Neither Dr. Cutler nor any other Plaintiff expert even attempts to identify the portion of orders that actually were at risk of diversion and/or that should not have been shipped after adequate diligence. In other words, no Plaintiff expert identifies the subset of orders that Distributors, after conducting adequate due diligence, would or should have determined to be based on illegitimate prescribing or dispensing, and therefore refused to ship. That missing piece is fatal to Plaintiffs' causation case because, as DEA itself has made clear, there is no basis to assume that an order initially flagged as "suspicious" is improper or at risk of diversion.[13]

Moreover, as described above, Plaintiffs' other experts demonstrate that the overwhelming majority of orders were ***not*** improper when viewed through a contemporaneous lens. Instead, they were based on prescribing by "well-intentioned and compassionate" doctors in accordance with the then-prevailing standard of care. *See* Br. 3, 9–10. Thus, no amount of due diligence by Distributors would or should have prevented those orders from ultimately being shipped.

The Opposition fails to dispute any of this. Plaintiffs effectively admit that they have no expert who (1) opines that, had Distributors conducted additional due diligence, it would or should have

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[12] Cutler Rpt. App. III.J at 2 ("[T]he share of harm potentially attributable to distributors can be calculated by applying an estimate of the *share of excessive shipments that distributors failed to identify*[.]" (emphasis in original)); Cutler Decl. ¶ 9; *see* Cutler Tr. 80:5–21 ("The percentages in Table J.1 were from Mr. McCann . . . it is not my opinion that these numbers are the correct numbers.").

[13] *See* Wright Tr. 208:5–24 (Dkt. 1972-12) (orders that meet regulatory definition of "suspicious" may well be "false positives" that do not pose a risk of diversion); Prevoznik Tr. 307:18–308:2 (Dkt. 1969-12) ("Q. [If] an order that is unusually large, does that order necessarily lead to diversion? A. [I]t may or may not.").

resulted in materially fewer pills reaching Ohio pharmacies, or (2) identifies which orders (or even what portion of orders in the aggregate) were inappropriate under prevailing treatment guidelines. Especially when viewed in light of Plaintiffs' explanation for why the vast majority of orders were based on legitimate prescribing, this failure of proof is fatal to Plaintiffs' claims against Distributors.

II. PLAINTIFFS' INJURIES ARE IMPERMISSIBLY REMOTE FROM DISTRIBUTORS' ALLEGED WRONGDOING.

Plaintiffs must establish a "***direct relation*** between the injury asserted and the injurious conduct alleged." *Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 268 (1992). Contrary to their suggestion, *e.g.*, Opp. 49–50, it is not enough, at the summary judgment stage, to ***allege*** that a direct relation exists (as this Court found they had done). Rather, Plaintiffs must come forward with ***evidence*** proving that Distributors' purported CSA violations (the only wrongful conduct identified by Plaintiffs) were a direct cause of their injuries. *See* Br. 5. The Opposition confirms that no such evidence exists.[14]

As Distributors demonstrated in their opening brief, the record evidence makes clear that there are at least ***five steps*** between Plaintiffs' injuries and Distributors' asserted wrongdoing:

> Step One: Distributors ship prescription opioids to licensed pharmacies.
>
> Step Two: Prescription opioids shipped by Distributors are (a) dispensed to a patient by a pharmacist (b) upon presentation of a bona fide prescription written in good-faith by a doctor based upon the then-prevailing standard of care.
>
> Step Three: Some portion of the pills are then illegally diverted—*i.e.*, they are sold or given away by the patient or are stolen from the patient's medicine cabinet.
>
> Step Four: A County resident illicitly uses the diverted opioids.
>
> Step Five: Plaintiffs suffer injuries (increased costs) as a result, for example, of addressing that individual's illegal activity, dependency, addiction or overdose.[15]

Plaintiffs do not dispute that at least two criminal acts—illicit diversion and illicit use—stand

[14] Distributors' opening brief showed that proof of a "direct relation" is required for each of Plaintiffs' claims. *See* Br. 14 n.32. The Opposition does not dispute that showing.

[15] *See* Br. 15–17. Plaintiffs have not come forward with any evidence that they were harmed as a result of any illicit prescribing or dispensing by rogue pharmacies or pill mill doctors. *See supra* at 1, 4.

between Distributors' shipment of FDA-approved medicines to licensed pharmacies and any potential increased expense they might occur. *See* Br. 17, 23. Under controlling Sixth Circuit precedent, this causal chain is too remote and attenuated. *E.g.*, *City of Cleveland v. Ameriquest Mortg. Secs.*, 615 F.3d 496 (6th Cir. 2010); *see Alston v. Advanced Brands & Importing Co.*, 494 F.3d 562, 565 (6th Cir. 2007) ("[T]he causal connection between the defendants' [alcohol] advertising and the plaintiffs' alleged injuries is broken by the intervening criminal acts of the third-party sellers and … underage purchasers.").

Plaintiffs relegate their discussion of *Ameriquest*—the most on-point decision by the Sixth Circuit on the issue of proximate causation under Ohio law—to a footnote. As the footnote concedes, the Sixth Circuit concluded in *Ameriquest* that the "too-attenuated chain of causation" and the presence of "so many independent actors" separating the defendants' conduct from Cleveland's injury established the absence of proximate causation. *See* Opp. 55 n.15. Tellingly, however, Plaintiffs do not even attempt to argue that the causal chain at issue here is less attenuated, or is intermediated by fewer independent actors, than in *Ameriquest*. Nor could they.

Ameriquest involved an attempt by an Ohio local government to recover costs incurred in responding to a "crisis" that "devastated its neighborhoods and economy." 615 F.3d at 499. Cleveland alleged that the defendants' financing of subprime loans led to an epidemic of foreclosure, which caused homes in the City to become "eyesores, fire hazards, and easy prey for looters and drug dealers," thereby leading to "increased expenditures for fire and police protection and maintenance and demolition costs" on the part of the City. *Id.* The Sixth Circuit held that the defendants' conduct was not a direct cause of the City's harm in part because the defendants did not sell loans directly to consumers. *Id.* at 504–05. It further observed, in support of its holding, that parties more directly responsible for the City's injuries included (i) the homeowners who voluntarily "chose to … default on their loans" and (ii) the "[d]rug dealers," "looters," and other "negligent or malicious" individuals who started fires at, sold drugs from, or vandalized abandoned homes. *See id.* at 505. As the Court

explained, the presence of these "independent actors between the alleged misconduct and the alleged injury" distinguished *Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136 (2002), and compelled the conclusion that the claims were "too indirect to warrant recovery." *Ameriquest*, 615 F.3d at 505–06.

This case is on all fours with *Ameriquest*. Like the defendants in *Ameriquest*, who "did not directly make subprime loans to the homeowners of Cleveland," Distributors do not make opioids available to patients. *Id.* at 505. Rather, a patient can obtain opioids only after a doctor makes an independent decision to write a prescription and a pharmacist makes the independent decision to fill the prescription. Moreover, myriad acts of wrongdoing by "so many independent actors" stand between Distributors' alleged wrongdoing and Plaintiffs' injuries. *See* Br. 15–17; *see also id.* at App. A (documenting approximately 1,200 separate examples of drug diversion by third parties in Summit and Cuyahoga Counties). Indeed, diversion necessarily entails at least one criminal act—whether by a doctor, pharmacist, patient or thief—that occurs sometime after a Distributor delivers medicines to a DEA-registered pharmacy. And a second criminal act (*i.e.*, illicit, non-prescribed use) necessarily occurs before Plaintiffs could possibly suffer any increased expense as a result of diversion. *See* Br. 17. Accordingly, the undisputed record evidence shows that the causal chain connecting Distributors' conduct to Plaintiffs' injuries is even more indirect and attenuated than the chain rejected by the Sixth Circuit as "too indirect" in *Ameriquest*.

Ameriquest also forecloses two additional arguments made by Plaintiffs. Plaintiffs assert that evidence purportedly showing that their injuries were the foreseeable consequence of Distributors' conduct creates a jury question regarding proximate causation. *See, e.g.*, Opp. 38–39. They similarly assert that their burden of proof should be lessened because Distributors "***intended***" for patients to use opioid medicines. Opp. 39–40.[16] As the Sixth Circuit explained, however, "the requirement of a

[16] There is no evidence that Distributors intended for anyone other than patients who obtained the medicines upon presentation of legitimate prescriptions to DEA-registered pharmacies to use opioids.

direct injury is … distinct from foreseeability and applies even if the Defendants intentionally caused the alleged course of events." *Ameriquest*, 615 F.3d at 502. Accordingly, the supposed fact that Distributors "knew about the consequences of" their purported failures to prevent diversion "***is not relevant to*** [***the***] ***directness requirement analysis***." *Id.* at 502–03.[17]

Plaintiffs claim that these intervening causal steps are "immaterial" because they are not "superseding causes," *e.g.*, Opp. 53–55, and that Distributors bear the burden of proof of establishing "superseding" causes. But, in order to prevail on summary judgment, Distributors need not prove that the (often criminal) conduct of third parties—*i.e.*, doctors, pharmacists, patients, illicit diverters, illicit end-users—are superseding or intervening causes. Instead, they must demonstrate only that the connection between their purported wrongdoing and Plaintiffs' injuries is remote and indirect. In *Ameriquest*, for example, the Sixth Circuit considered the intervening (sometimes criminal) conduct of third party lenders, homeowners, arsonists, looters and drug dealers not to hold that they were superseding or intervening causes, but to conclude that the plaintiffs failed to "satisfy the directness requirement." 615 F.3d at 504; *accord Hemi Grp., LLC v. City of New York, N.Y.*, 559 U.S. 1, 11 (2010) (directness requirement not satisfied where city's harm was contingent upon acts of third parties who failed "to pay taxes they were legally obligated to pay"). The same conclusion is warranted here.

Rather than grapple meaningfully with *Ameriquest*, Plaintiffs point to the Sixth Circuit's earlier, inapposite decision in *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602 (6th Cir. 2004). Opp. 39, 50. Unlike *Ameriquest*, that case did not involve claims brought by a local government to recover for increased costs incurred in combatting a social crisis. Instead, the employee-plaintiffs in *Trollinger* alleged that

[17] Plaintiffs assert that "proximate causation is broader with regard to intentional acts than it is for negligent acts." Opp. 40 (citing *Iron Workers Local Union No. 17 Ins. Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 771, 783 (N.D. Ohio 1998)). But *Iron Workers* concerns intentional torts, and Plaintiffs do not adduce any evidence that Distributors intended to cause anyone harm. Nothing about Distributors' supposed intent that FDA-approved medicines reach the patients to whom they were legitimately prescribed provides any basis for relieving Plaintiffs of their obligation to prove a direct connection between their injuries and Distributors' wrongful conduct.

their employer engaged in a scheme to deflate their wages by hiring illegal alien workers. The Sixth Circuit declined to dismiss the complaint at the pleading stage, but only after noting that the defendant allegedly "***directly*** employed the four plaintiffs, … ***directly*** paid them and … ***directly*** injured [them] by paying them less than they otherwise would have paid" but for the illegal hiring scheme. *Id.* at 615. Accordingly, the connection between Distributors' conduct and Plaintiffs' injuries on the evidentiary record currently before the Court is far more attenuated and indirect than the connection alleged in *Trollinger*.[18]

Finally, Plaintiffs assert that Distributors' summary judgment motion should be denied because the Court denied a supposedly "parallel" motion to dismiss filed by Manufacturers. Opp. 49–50. That is nonsense. As explained above, Plaintiffs now admit that Distributors did not engage in the Manufacturer marketing conduct alleged in the Complaint. And the sufficiency of Plaintiffs' allegations at the pleadings stage is irrelevant on summary judgment. The question now is one of evidence. Because the record is chock-full of evidence regarding the numerous actors and events that separate Distributors' conduct from Plaintiffs' injuries, and because Plaintiffs have not come forward with any evidence that Distributors' conduct was a direct cause of those injuries, the Court should grant Distributors' motion for summary judgment.

III. DISTRIBUTORS DID NOT CAUSE PLAINTIFFS TO INCUR EXPENSES FLOWING FROM THE ABUSE OF NON-PRESCRIPTION OPIOIDS.

Plaintiffs do not deny that their claimed harm stems in substantial part from the abuse of non-prescription opioids such as heroin and illicit fentanyl. Nor do they dispute that Distributors play no role in supplying illegal drugs, either directly or indirectly, to Ohio residents. *See* Br. 22 & n.42.

[18] Plaintiffs' reliance on *Direct Sales Co. v. United States*, 319 U.S. 703, 710–11 (1943), is even more strained. That case does not hold that that there is an "inherent causal relationship" between diversion of opioids and harm to the public. Opp. 36, 39. Rather, *Direct Sales* merely observes that it may be easier to prove a conspiracy between buyers and sellers of "restricted products" like "narcotics" than buyers and sellers of "sugar, cans, and other articles of normal trade[.]" 319 U.S. at 711.

Especially given that concession, the connection between costs incurred by Plaintiffs to combat the illegal use of street drugs and Distributors' alleged wrongdoing is far too indirect and attenuated under settled law. Plaintiffs' argument to the contrary lacks merit.

Plaintiffs argue that Distributors are the proximate cause of their injuries because there is a "link between prescription opioid exposure and the subsequent use of heroin and other illicit opioids." Opp. 79. But a correlation between opioid exposure and the abuse of illegal street drugs does not even come close to satisfying Plaintiffs' burden of proving a "direct relation."

First, to the extent that Plaintiffs argue that "[t]he massive increase of opioids shipped purportedly ***for medical uses*** caused increased non-medical use (diversion and abuse)," Opp. 76, that argument has nothing to do with Distributors. Distributors are not alleged to have caused the increase in prescriptions for medical uses, and as explained above, they had no ability, and certainly no duty, to control or stem shipments of prescription opioids that were prescribed by doctors for the legitimate medical uses of the doctors' patients. *See supra* at 5.

Second, the causal chain relied on by Plaintiffs boils down to the following: (1) Distributors ship prescription drugs to pharmacies, (2) the medicines are properly dispensed pursuant to a legitimate prescription, (3) they are then diverted to an illicit market, (4) a third party illegally ingests the pills and becomes addicted, (5) the third party transitions from prescription opioids to an illegal street drug, (6) the third party is harmed by the street drug, and (7) Plaintiffs incur expenses in responding to the third party's illicit use.[19] This chain is too attenuated and intermediated by the actions of too many independent actors to survive under *Ameriquest*.

[19] To be sure, it is possible that the patient to whom the medicines were prescribed might herself become addicted and later turn to heroin of illicit fentanyl. But in that case, Distributors' alleged duty to prevent diversion is not implicated *at all*. Diversion does not occur if a patient becomes addicted while under the care of a doctor who legitimately prescribes opioids pursuant to the prevailing standard of care.

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Respectfully Submitted,

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I, Geoffrey E. Hobart, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record.

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